Senate Finance, Ways and Means Committee 1

Amendment No. 2 to SB0777

Watson
Signature of Sponsor

AMEND Senate Bill No. 777 House Bill No. 717*

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. Tennessee Code Annotated, Section 33-2-402(10)(A), is amended by deleting the language "to fifty percent (50%) or more of its patients and to one hundred fifty (150) or more patients" and substituting instead the language "to twenty-five percent (25%) or more of its patients or to one hundred fifty (150) or more patients".

SECTION 2. Tennessee Code Annotated, Section 33-2-402(10), is amended by adding the following as a new subdivision (C):

(C) "Nonresidential office-based opiate treatment facility" does not include any facility that meets the definition of a nonresidential substitution-based treatment center for opiate addiction;

SECTION 3. Tennessee Code Annotated, Section 33-2-403, is amended by adding the following new subsections:

(h) By January 1, 2019, the commissioner of mental health and substance abuse services shall revise rules for nonresidential office-based opiate treatment facilities to be consistent with state and federal law and to establish:

(1) Standards for determining what constitutes a high dose of the opioid employed in treatment at a nonresidential office-based opiate treatment facility;

(2) Protocols for initiating or switching a patient at a nonresidential office-based treatment facility to a high dose of the opioids employed in treatment; and

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(3) Protocols for initiating periodic prescriber-initiated-and-led discussions with patients regarding patient readiness to taper down or taper off the opioids employed in treatment.

(i) The commissioner is authorized to use emergency rulemaking under § 4-5-208 to promulgate the rules pursuant to subsection (h). The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(j)

(1) Beginning in 2020, the commissioner of mental health and substance abuse services shall review the rules for nonresidential office-based opiate treatment facilities by September 30 of each even-numbered year.

(2) The commissioner of mental health and substance abuse services shall submit the rules for nonresidential office-based opiate treatment facilities to each health-related board that licenses any practitioner authorized by the state to prescribe the products for the treatment of an opioid use disorder as defined in the Diagnostic and Statistical Manual of Mental Disorders and to the board of pharmacy.

(3)

(A) Each board shall review the rules and enforce the rules with respect to that board's licensees.

(B) When a board's licensees are subject to the rules for nonresidential office-based opiate treatment facilities, the definition of "enforce" for purposes of this subdivision (j)(3) means referring any complaints or information regarding those licensees to the department.

(4) Each board shall post the rules on the licensing board's website.

(k)

(1) The commissioner of mental health and substance abuse services shall provide a copy of any emergency rule developed pursuant to subsection (h) or (i) and any revision to a rule developed pursuant to subsection (j) to the chairs of the health committee of the house of representatives and the health and welfare committee of the senate at the same time the rules are submitted to the licensing boards pursuant to subdivision (j)(2).

(2) The commissioner of mental health and substance abuse services shall provide a copy of any rule developed pursuant to subsection (h) or (j) and any revision to a rule developed pursuant to subsection (j) to the chairs of the health committee of the house of representatives and the health and welfare committee of the senate at the same time the text of the rule is made available to the government operations committees of the senate and the house of representatives for purposes of conducting the review required by § 4-5-226 in order for the health committee of the house of representatives and the health and welfare committee of the senate to be afforded the opportunity to comment on the rule.

(l) A violation of a rule described in subsection (h) and (j) is grounds for disciplinary action against a practitioner licensed under title 63 by the board that licensed that practitioner.

SECTION 4. Tennessee Code Annotated, Section 33-2-406(h), is amended by designating the existing language as subdivision (h)(1) and adding the following as a new subdivision (h)(2):

(2)

(A) Notwithstanding this part, beginning July 1, 2018, the licensing fee for a nonresidential office-based opiate treatment facility is one thousand five hundred dollars ($1,500) per year. On or after July 1, 2019, the department may revise the fee by rule as otherwise permitted by law.

(B) Notwithstanding this part, beginning July 1, 2018, the department shall apply a reinspection fee of five hundred dollars ($500) to a nonresidential office-based opiate treatment facility. On or after July 1, 2019, the department may revise the fee by rules as otherwise permitted by law.

SECTION 5. Tennessee Code Annotated, Section 63-1-403, is amended by adding the following as subsection (c) and redesignating existing subsection (c) and remaining subsections accordingly:

(c) By July 1, 2019, the commissioner of mental health and substance abuse services, in collaboration with the commissioner of health, shall revise the nonresidential buprenorphine treatment guidelines to be consistent with state and federal law and establish protocols for initiating periodic prescriber-initiated-and-led discussions with patients regarding patient readiness to taper down or taper off opioids employed in treatment. The commissioner of mental health and substance abuse services shall consult with appropriate physicians, alcohol and substance abuse counselors, and other experts to serve as resources in the development of guidelines under this subsection (c).

SECTION 6. Tennessee Code Annotated, Section 53-10-304, is amended by adding the following as a new subsection (e):

(e) Notwithstanding subsection (c) or (d), a healthcare practitioner shall submit the dispensing of buprenorphine products in accordance with this part. However, this subsection (e) does not apply to a practitioner when reporting the dispensing of buprenorphine products would conflict with 42 CFR part 2.

SECTION 7. Tennessee Code Annotated, Section 53-11-311, is amended by adding the following as a new subsection:

( )

(1)

(A) Notwithstanding any other law, the dispensing of buprenorphine products is prohibited by any person or entity unless the dispensing is done by a nonresidential office-based opiate treatment facility, as defined in § 33-2-402, with approval from the department of mental health and substance abuse services, a nonresidential substitution-based treatment center for opiate addiction as defined in § 33-2-402, a pharmacy licensed under title 63, chapter 10, or a hospital licensed under title 33, or title 68, chapter 11. This subsection ( ) does not apply to the administering of buprenorphine products as otherwise permitted by law.

(B) A pharmacy and a distributor, as defined in § 63-10-204, shall report to the department of health the quantities of buprenorphine that the pharmacy or distributor delivers to nonresidential office-based opiate treatment facilities in this state.

(2) The department of mental health and substance abuse services shall promulgate rules to establish requirements for approval of dispensing of buprenorphine products at a nonresidential office-based opiate treatment facility as defined in § 33-2-402. These rules shall include a requirement that a provider

who dispenses buprenorphine products at a nonresidential office-based opiate treatment facility must report the fact that the provider dispenses buprenorphine products to the provider's licensing board, check the controlled substance database prior to dispensing, and enter the amounts dispensed into the controlled substance database, to the extent permitted by 42 CFR part 2.

SECTION 8. Tennessee Code Annotated, Section 68-1-128(a)(1), is amended by deleting the language "controlled substances in the previous calendar year" and substituting instead the language "controlled substances, other than buprenorphine formulations that have not received approval for pain applications from the federal food and drug administration, in the previous calendar year".

SECTION 9. Tennessee Code Annotated, Section 68-1-128(a)(1), is amended by designating the existing language as subdivision (a)(1)(A) and adding the following as a new subdivision (a)(1)(B):

(B) Identify the top twenty (20) prescribers who have unique DEA numbers of buprenorphine products or equivalent products in the previous calendar year, or if implemented more frequently for the relevant time period as determined by the department, from the data available in the controlled substances database established pursuant to title 53, chapter 10, part 3. The department may organize the list of prescribers required by this subdivision (a)(1)(B) in any manner as may be appropriate to reflect levels of service, training, or other relevant factors by a healthcare provider. These factors may include, but not be limited to, whether the provider is board-certified.

SECTION 10. Tennessee Code Annotated, Section 68-1-128(a)(3), is amended by deleting the language "list" and substituting the language "lists".

SECTION 11. Tennessee Code Annotated, Section 68-1-128(b)(1)(A), is amended by deleting the language "on the top fifty (50) prescribers of controlled substances in the state and

the top ten (10) prescribers" and substituting instead the language "on the lists of the top twenty (20) prescribers of buprenorphine products, the top fifty (50) prescribers of controlled substances in the state, and the top ten (10) prescribers".

SECTION 12. Tennessee Code Annotated, Section 68-1-128, is amended by adding the following as new subsections:

(h)

(1) After the completion of the study provided for in subdivision (i)(1), and no later than July 31 of each subsequent year, in consultation with the controlled substance database, the department of health shall identify licensed prescribers whose prescribing patterns of controlled substances represent statistical outliers in addition to top prescribers and high-risk prescribers identified pursuant to this section.

(2) The department of health shall inquire of the appropriate licensing board concerning any action taken against a prescriber identified by the department pursuant to subdivision (h)(1). Each board shall respond within thirty (30) days concerning the status of any action or lack of action against an identified prescriber.

(3) Each board shall also report on the total numbers of prescribers disciplined each year and the general categories of discipline imposed on the prescribers, including consent agreements, as well as reasons for declining to exercise discipline.

(4) The commissioner of health shall report a summary of the data concerning prescribers identified under this subsection (h), including a summary of any disciplinary action taken or pending by a licensing board against a prescriber, to the chairs of the health and welfare committee of the senate and the health committee of the house of representatives.

(i)

(1) On or before January 1, 2020, the comptroller of the treasury shall complete a study of the incidence of significantly statistically abnormal prescribing patterns by prescribers licensed under title 63 and the disciplinary response of the licensing boards to those prescribers. The comptroller shall report findings and recommendations of the study to the chairs of the health and welfare committee of the senate and the health committee of the house of representatives.

(2) Notwithstanding any other state law, the department of health, the controlled substance database, and a licensing board of any prescriber of opioids shall disclose to the comptroller of the treasury any relevant information in order for the comptroller to complete this study from July 1, 2018, through June 30, 2020. Any record that personally identifies a patient or a healthcare practitioner that is disclosed to the comptroller shall be confidential and shall not be disclosed as a public record at any time and shall not be subject to a subpoena.

SECTION 13. Tennessee Code Annotated, Title 63, Chapter 1, Part 1, is amended by adding the following as a new section:

(a) If a healthcare practitioner treats a human patient with an opioid and that healthcare practitioner's licensing board or agency finds that the healthcare practitioner engaged in a significant deviation or pattern of deviation from sound medical judgment, the minimum disciplinary action that a healthcare practitioner's licensing board or committee must take shall be established and promulgated by rule by a task force composed of representatives from:

(1) The board of medical examiners;

(2) The board of osteopathic examination;

(3) The board of dentistry;

(4) The board of podiatric medical examiners;

(5) The board of optometry;

(6) The board of nursing; and

(7) The board of medical examiners' committee on physician assistants.

(b) The task force must create a uniform minimum disciplinary action pursuant to this section, which shall be binding on each board and committee listed in subsection (a).

(c) The task force is authorized to establish minimum disciplinary actions pursuant to this section by emergency rule in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5. The rule promulgated by the task force shall be codified and published by the secretary of state in each of the chapters for the boards and committee listed in subsection (a).

(d)

(1) Each board and committee listed in subsection (a) must select and appoint by majority vote one (1) member of their respective board or committee to serve on the task force before September 1, 2018.

(2) The task force shall select and appoint a member to serve as chair of the task force.

(3) A majority of the task force shall constitute a quorum, and a majority vote of the task force members present is required for any action.

(4) Notwithstanding any provision of the Uniform Administrative Procedures Act to the contrary, the task force shall hear public comment at any required hearing on behalf of all boards listed in subsection (a) when a hearing is required. The task force is authorized to vote to promulgate the rule to establish the uniform minimum disciplinary action for each board and committee listed in subsection (a).

(e) In the event that the task force has not promulgated uniform minimum disciplinary actions by April 1, 2019, then the minimum disciplinary action that a healthcare practitioner's licensing board or agency must take is a removal of the healthcare practitioner's right to prescribe controlled substances for no less than five (5) years.

(f) The task force shall terminate upon the later of July 1, 2019, or the effective date of a permanent rule establishing the uniform minimum disciplinary action pursuant to this section. The procedures of this section must be followed to amend, repeal, or otherwise revise the uniform minimum disciplinary action established pursuant to this section. In such case, the task force may be reconvened by the commissioner of health or a majority of the boards and committees listed in subsection (a).

(g) Nothing in this part shall be construed to prohibit the licensing boards and committee listed in subsection (a) from promulgating rules regarding other minimum disciplinary actions that will be taken against their licensees.

SECTION 14. Section 13 of this act shall terminate on July 1, 2023, and the law in effect prior to this act's effective date shall be restored.

SECTION 15. For rulemaking purposes, this act shall take effect upon becoming a law, the public welfare requiring it. For all other purposes, this act shall take effect July 1, 2018, the public welfare requiring it.